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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 03/20/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/701,453

Applicant(s)

Granoff et al.

Examiner

S. Devi, Ph.D.

Art Unit

1645



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 17, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 16 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 12. 6) ☐ Other:

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendment

- 1) Acknowledgment is made of Applicants' amendment filed 12/17/02 (paper no. 14) in response to the non-final Office Action mailed 06/13/02 (paper no. 11).

Status of Claims

- 2) Claim 15 has been canceled via the amendment filed 12/17/02.

Claims 1-14 and 16 are pending and are under examination.

Information Disclosure Statement

- 3) Acknowledgment is made of Applicants' Information Disclosure Statement filed 09/25/02 (paper no. 12). The information referred to therein has been considered and a signed copy is attached to this Office Action (paper no. 15).

Drawings

- 4) The drawings are objected to under 37 C.F.R. 1.84 because of the reasons set forth by the Draftsperson in the attached Form PTO 948 (paper no. 15). Correction is required. Applicants are asked to note the changes effected 03 May 2001, particularly the changes to the 'Timing of Corrections':

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

A. Correction of Informalities -- 37 CFR 1.85; 1097 O.G. 36

New formal drawings must be filed with the changes incorporated therein. The art unit number, application number (including series code) and number of drawing sheets should be written on the reverse side of the drawings. Applicant may delay filing of the new drawings until receipt of the "Notice of Allowability" (PTOL-37 or PTO-37). If delayed, the new drawings MUST be filed within the THREE MONTH shortened statutory period set for reply in the "Notice of Allowability" to avoid extension of time fees. Extensions of time may be obtained under the provisions of 37 C.F.R. 1.136(a) for filing the corrected drawings (but not for payment of the issue fee). The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

B. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the three month shortened statutory period set in the "Notice of Allowability" (PTO-37). Within that three month period, two weeks should be allowed for review of the new drawings by the Office. If a correction is determined to be unacceptable by the Office, Applicant must arrange to have an acceptable correction re-submitted within the original three month period to avoid the necessity of obtaining an extension of time with extension fees. Therefore, applicant should file corrected drawings as soon as possible.

Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.

Abstract

5) This application currently does not contain an abstract of the disclosure as required by 37 C.F.R 1.72(b). However, as this application is a 371 of application of PCT/US99/11977, a copy of the published abstract from this application is placed in the instant application as page number 13. If Applicants desired changes to the abstract, such changes should be directed to the abstract of the PCT/US99/11977.

Specification

6) The specification is objected to for the following reason(s):

The use of the trademark in the instant specification has been noted in this application. For example, see page 4, line 21: "Tween 80"; and page 4, line 22: "Span 85". The recitation should be capitalized wherever it appears and be accompanied by the generic terminology. Each letter of the trademark must be capitalized. See M.P.E.P 608.01(V) and Appendix I. Although the use of trademarks is permissible in patent applications, the propriety nature of the trademarks should be

respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. It is suggested that Applicants examine the whole specification to make similar corrections to trademark recitations, wherever such recitations appear.

Rejection(s) Moot

7) The rejection of claim 15 maintained by the previous Examiner in paragraph 1 of the Office Action mailed 06/13/02 (paper no. 11) under 35 U.S.C § 112, first paragraph, as being non-enabled, is moot in light of Applicants' cancellation of the claim.

8) The rejection of claim 15 made by the previous Examiner in paragraph 3 of the Office Action mailed 06/13/02 (paper no. 11) under 35 U.S.C § 103(a) as being unpatentable over Milagres *et al.* in view of Lieberman *et al.* is moot in light of Applicants' cancellation of the claim.

Rejection(s) Withdrawn

9) The rejection of claim 1 maintained by the previous Examiner in paragraph 1 of the Office Action mailed 06/13/02 (paper no. 11) is withdrawn upon further consideration.

10) The rejection of claims 1-14 and 16 made by the previous Examiner in paragraph 3 of the Office Action mailed 06/13/02 (paper no. 11) under 35 U.S.C § 103(a) as being unpatentable over Milagres *et al.* in view of Lieberman *et al.* is withdrawn upon further consideration.

Rejection(s) under 35 U.S.C § 112, Second Paragraph

11) Claims 8-14 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite, for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 8 is vague and indefinite in the recitation 'administering composition of claim 1', because it is unclear to whom or to what the composition is being administered.

(b) Claims 9-14, which depend directly or indirectly from claim 8, are also rejected as being indefinite, because of the vagueness or indefiniteness identified above in the base claim.

Rejection(s) under 35 U.S.C § 103

12) Claims 1-14 and 16 are rejected under 35 U.S.C § 103(a) as being unpatentable over Granoff *et al.* (*Infect. Immun.* 65: 1710-1715, 01 May 1997 - Applicants' IDS) (Granoff *et al.*, 1997) or Costantino *et al.* (*Vaccine* 10: 691-698, 1992) and Milagres *et al.* (*FEMS Immunol. Med. Microbiol.* 13: 9-17, 1996 - Applicants' IDS) in view of Granoff *et al.* (*Vaccine* 11: S46-S51, 1993) (Granoff *et*

al., 1993) or Blake *et al.* (US 6,451,317, filed 09/08/1997).

Granoff *et al.* (1997) taught a group C *Neisseria meningitidis* oligosaccharide-CRM₁₉₇ conjugate vaccine contained in aluminum hydroxide or alum (i.e., second carrier) and a method of inducing an immune response to group C *Neisseria meningitidis* by administering an immunologically effective amount of the vaccine (see abstract; and 'Materials and Methods'). Granoff *et al.* (1997) taught that one approach to increasing both the immunogenicity and the effectiveness of PS-protein conjugate vaccines is the use of an adjuvant and that an effective adjuvant may permit the use of lower dosages and fewer injections, thereby decreasing the cost of an immunization program (see paragraph bridging left and right columns on page 1710). Granoff *et al.* (1997) suggested the use of their conjugate vaccine 'in combination' with other vaccines (see right column on page 1714).

Costantino *et al.* taught a conjugate vaccine comprising group C meningococcal oligosaccharides conjugated to CRM 197 and aluminium hydroxide and a method of inducing an immune response to group C *Neisseria meningitidis* by administering an immunologically effective amount of the vaccine (see page 693).

Granoff *et al.* (1997) do not teach the use of a group B *Neisseria meningitidis* outer membrane protein or vesicles along with their conjugate vaccine.

Milagres *et al.* taught the use of group B meningococcal outer membrane proteins as alternative immunogens against group B meningococci (see page 9). Milagres *et al.* taught group B meningococcal outer membrane vesicle vaccines containing less than 10% LOS for use in an improved meningococcal B and C vaccine. Milagres *et al.* also taught a method of immunizing by administering an immunologically effective amount of their vaccine (see page 15; and 'Materials and Methods').

Granoff *et al.* (1993) taught that group B meningococcal OMP contains ~~and~~ a number of membrane-associated proteins, and that it enhances immune response by its adjuvant activity (see Table 1; and page S48, right column)

Blake *et al.* disclosed the use of meningococcal OMV as an adjuvant capable of direct T cell stimulation, or immunopotentialiation (see first full paragraph in column 3; and fourth full paragraph in column 2).

Given the express teaching of Blake *et al.* that meningococcal OMV serves as an adjuvant capable of direct T cell stimulation, or immunopotentialization, and the teaching of Granoff *et al.* (1993) that group B meningococcal OMP enhances immune response by its adjuvant activity, and the explicit suggestion by Granoff *et al.* (1997) that their conjugate vaccine can be used in combination with other vaccines, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine Milagres's group B meningococcal outer membrane protein or outer membrane vesicle vaccine with Granoff's or Costantino's group C *Neisseria meningitidis* oligosaccharide-CRM₁₉₇ conjugate vaccine to produce the instant invention, with a reasonable expectation of success. Since one of skill in the art would readily understand that Granoff's (1997) or Costantino's group C meningococcal oligosaccharide-containing vaccine would not induce immunity against group B meningococci, a major causative agent of meningitis, a skilled artisan would have been motivated to combine it with Milagres's immunopotentiating group B meningococcal outer membrane protein or outer membrane vesicle vaccine to produce the instant invention for the expected benefit of producing an improved vaccine against both group B and C meningococci as taught by Milagres *et al.*

Claims 1-14 and 16 are *prima facie* obvious over the prior art of record.

Relevant Prior Art

13) The prior art made of record and not currently relied upon in any of the rejections is considered pertinent to Applicants' disclosure:

- Granoff (US 6,413,520) taught a conjugate vaccine comprising meningococcal C oligosaccharides and CRM₁₉₇ protein with or without aluminum hydroxide or MF59 (see entire document).

Remarks

14) Claims 1-14 and 16 stand rejected.

15) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242, which is able to receive transmissions 24 hours a day and 7 days a week. The RightFax

Serial Number: 09/701,453
Art Unit: 1645

number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

16) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A telephone message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

March, 2003


S. DEVI, PH.D.
PRIMARY EXAMINER